510(k) Summary

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

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Date of Preparation: 2013-01-20

Proprietary Name: Patient Monitor (Models iM60 and iM70)

Classification:

Description	Classification	Product code
21 CFR 870.1025 Arrhythmia detector and alarm (Including ST-segment measurement and alarm)	II	MHX
21 CFR 870.2300 Cardiac monitor (including cardiotachoment and rate alarm)	II	DRT
21 CFR 870.1130 Non-Invasive blood pressure measurement System	II	DXN
21 CFR 870.1110 Blood pressure computer	II	DSK
21 CFR 880.2910 Clinical Electronic Thermometers-Temperature Monitor with Probe	II	FLL
21 CFR 870.2700 Oximeter, Pulse	II	DQA
21 CFR 870.1400 Carbon Dioxide Gas Analyzer	II	CCK
21 CFR 868.1500 Enflurane gas analyzer	II	CBQ
21 CFR 868.1620 Halothane gas analyzer	II	CBS
21 CFR 868.1700 Nitrous Oxide gas analyzer	II	CBR
21 CFR 868.1720 Oxygen gas analyzer	II	CCL
21 CFR 868.2900 cable, transducer and electrode, patient, (including	II	DSA

connector)		
21 CFR 870.2300 monitor, cardiac (incl. cardiotachometer & rate alarm)	II	DRT
21 CFR 870.1025 Detector and Alarm, Arrhythmia	II	DSI
21 CFR 870.1025 Monitor, ST Segment with Alarm	II	MLD

Regulatory Class: Class II

Legally Marketed Predicate Devices:

Manufacturer	Predicate Device	510(k) number	Cleared date
Edan Instruments, Inc	iM50	K113623	Feb.1.2012
Edan Instruments, Inc	iM80	K113623	Feb.1.2012

Device Description: iM60/iM70 Patient Monitor can perform long-time continuous monitoring of multiple physiological parameters. Also, it is capable of storing, displaying, analyzing and controlling measurements, and it will indicate alarms in case of abnormity so that doctors and nurses can deal with them in time.

iM60 is outfitted with a 10.4-inch display screen, iM70 is 12.1-inch, as well as an equally large touch screen, which enables the operation by touching the screen, thus offering convenience for doctors and nurses.

iM60 Patient Monitor has parameter modules including SpO_2 (pulse oxygen saturation, pulse rate and SpO_2 plethysmogram) with EDAN SpO_2 module or Nellcor SPO2 module, NIBP, TEMP, ECG, RESP, $EtCO_2$, IBP and C.O..

iM70 Patient Monitor has parameter modules including SpO_2 with EDAN SpO_2 module or Nellcor SPO_2 module, NIBP with EDAN NIBP module or Omron M3600, TEMP, ECG, RESP, $EtCO_2$, C.O., IBP, AG.

Comparison with predicate device

The iM60 and iM70 Patient Monitors have the following similarities to that which previously received 510(k) concurrence:

- have the same indications for use,
- use the same operating principle,
- have the same testing module, e.g. EDAN SpO_2 module and Nellcor NELL-1 module.
- have the same or similar performance specifications

In summary, the iM60 and iM70 Patient Monitor described in this submission are substantially equivalent to the predicate device.

Intended Use:

iM60:
The iM60 monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (CO), Temperature (dual-TEMP) and Expired CO2. The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.
iM70:
The iM70 monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (CO), Temperature (dual-TEMP), Expired CO2 and Anesthetic gas (AG). The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

Contraindications: It is not intended for use in patient's home or residence, or when it has not been ordered by a physician.

Test Summary: The following quality assurance measures were applied to the development of the Patient Monitor

- Software testing
- Hardware testing
- Safety testing
- Environment test
- Risk analysis
- Final validation

Conclusion:

Verification and validation testing was done on the Patient Monitor. This premarket notification submission demonstrates that Patient Monitor is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 20, 2014

Edan Instruments, Inc.
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Certification Engineer
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Re: K131971
Trade/Device Name: iM60/iM70 Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including St-Segment Measurement And Alarm
Regulatory Class: Class II
Product Code: MHX, DRT, DXN, DSK, FLL, DQA, CCK, CBQ, CBS, CBR, CCL, DSA, DSI, MLD
Dated: February 7, 2014
Received: February 10, 2014

Dear Ms. Sun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K131971

Device Name: Patient Monitor Models iM60 and iM70

iM60:

The iM60 monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (CO), Temperature (dual-TEMP) and Expired CO2. The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

iM70:

The iM70 monitor monitors parameters such as ECG (3-lead, 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (2/4 channels IBP NIBP), Cardiac Output (CO), Temperature (dual-TEMP), Expired CO2 and Anesthetic gas (AG). The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

Prescription Use ___×___ And/Or Over the Counter Use _____

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.03.20 10:38:47 -04'00'

for Bram Zuckerman